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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,214	06/22/2001	Hayao Tanaka	210131US0PCT	5190

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EXAMINER
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AUGHENBAUGH, WALTER

ART UNIT	PAPER NUMBER
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1772

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action  
Before the Filing of an Appeal Brief**

Application No.

09/857,214

Applicant(s)

TANAKA, HAYAO

Examiner

Walter B. Aughenbaugh

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**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 11 May 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**NOTICE OF APPEAL**

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

**AMENDMENTS**

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☒ Applicant's reply has overcome the following rejection(s): see continuation sheet.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: none.  
Claim(s) objected to: none.  
Claim(s) rejected: 6 and 12.  
Claim(s) withdrawn from consideration: none.

**AFFIDAVIT OR OTHER EVIDENCE**

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

**REQUEST FOR RECONSIDERATION/OTHER**

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_  
12. ☒ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). 05112005  
13. ☐ Other: \_\_\_\_\_

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**ADVISORY ACTION**

***Acknowledgement of Applicant's Amendments***

1. The amendment made in claim 12 in the After Final Amendment filed May 11, 2005 (Amdt. D) has been received, considered and entered by Examiner.
2. The cancellation of claim 7 in Amdt. D has been entered by Examiner.

***WITHDRAWN REJECTIONS***

***Claim Rejections - 35 USC § 112***

3. The 35 U.S.C. 112 rejection of claim 7 that was repeated in paragraph 2 of the previous Office Action mailed January 11, 2005 has been withdrawn due to the cancellation of claim 7 in Amdt. D.
4. The 35 U.S.C. 112 rejection of claim 7 made of record in paragraph 5 of the previous Office Action mailed January 11, 2005 has been withdrawn due to the cancellation of claim 7 in Amdt. D.
5. The 35 U.S.C. 112 rejection of claim 12 made of record in paragraph 5 of the previous Office Action mailed January 11, 2005 has been withdrawn due to Applicant's amendment in claim 12 in Amdt. D.

***Claim Rejections - 35 USC § 103***

6. The 35 U.S.C. 103 rejections of claim 7 that were repeated in paragraph 4 of the previous Office Action mailed January 11, 2005 have been withdrawn due to the cancellation of claim 7 in Amdt. D.

***REPEATED REJECTIONS***

***Claim Rejections - 35 USC § 112***

7. The 35 U.S.C. 112 rejection of claim 12 that was repeated in paragraph 3 of the previous Office Action mailed January 11, 2005 has been repeated for the reasons previously made of record.

***Claim Rejections - 35 USC § 103***

8. The 35 U.S.C. 103 rejections of claims 6 and 12 that were repeated in paragraph 4 of the previous Office Action mailed January 11, 2005 have been repeated for the reasons previously made of record.

***Response to Arguments***

9. Applicant's arguments presented on pages 4-6 of Amdt. D have been fully considered but are not persuasive.

Applicant misrepresents the position of the Office in the last full sentence of page 4 of Amdt. D where Applicant states that "[i]t is the Examiner's position that the saturation adsorption amount is a function of the molecules placed into the container and not of the polymer used in the container". It has been the position of the Examiner throughout the prosecution of this application that saturation adsorption amount is dependent upon the identity and certain properties of the molecules placed into the container in solution and also upon the polymer of the container, not that the saturation adsorption amount is not a function of "the polymer used in the container". Examiner's statement that "[t]he saturation adsorption amount is not solely a function of the material that coats the container" on page 5 of the previous Office Action mailed January 11, 2005 is an indication that the Office recognizes that the saturation adsorption amount is

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dependent upon the material that coats the container (i.e. “the polymer used in the container” in Applicant’s terminology used in the last full sentence of page 4 of Amdt. D, also see language of claim 12: “coated with an ultra-hydrophilic polymer”).

Applicant states on page 5 of Amdt. D that the “-in terms of concentration of the solution, temperature, and pH of the solvent-” statement made on pages 7 and 8 of the specification “is not intended to define the saturation adsorption amount as being solution dependent”, but lines 22-26 of page 7 and lines 9-16 of page 8 of the specification read as if Applicant did intend the saturation adsorption amount to be “solution dependent”. The statement “is always  $1 \times 10^{-1}$  pmol/cm<sup>2</sup> or less at the diluted concentration of serum” in lines 4-5 of page 8 of the specification further indicates that Applicant intended the saturation adsorption amount to be “solution dependent”.

Furthermore, Examiner’s position remains that the saturation adsorption amount of the container depends upon both the material that coats the container and the identity and certain properties of the molecules placed into the container in solution. See again paragraph 7 of the previous Office Action mailed January 11, 2005, which is provided below:

The saturation adsorption amount is not solely a function of the material that coats the container. Proteins that have differing degrees of hydrophilicity will have differing affinities for the material that coats the container. Applicant states that the word “saturation” in the phrase “saturation adsorption amount” makes the “saturation adsorption amount” a “fixed quantity relating to a maximum adsorption amount that a given coated surface can support irrespective of the conditions assayed”, but the saturation adsorption amount varies with the type of molecule (moreover, the particular protein). A first protein with a higher affinity for a particular coating material than that of a second protein will show a higher adsorption amount upon saturation of the protein within a given surface area of the coating material than the second protein, all other conditions being equal.

Applicant’s statement that “the saturation adsorption amount is determined by the combination of the properties of the molecules existing in the container and the base material” in lines 20-22 of page 5 of Amdt. D supports Examiner’s position that the saturation adsorption amount of the

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container depends upon both the material that coats the container and the identity and certain properties of the molecules placed into the container in solution. Applicant's conditional statements in the first full paragraph of page 6 of Amdt. D (e.g. "if the surface of the container contains no hydrophobic moiety and carries no electric charge") are not persuasive because Applicant does not address proteins which have hydrophilic moieties, which would have an affinity to an "ultra-hydrophilic polymer" as claimed, and the discussion regarding electric charge is not related to Applicant's claimed subject matter (i.e. there is no indication of the charge of the "ultra-hydrophilic polymer" as claimed in the application).

In response to Applicant's arguments in the last full paragraph of page 6 of Amdt. D, Claim 12 is indefinite because the metes and bounds of the claim cannot be ascertained since the types of proteins (e.g. hydrophobic or hydrophilic, positively charged or negatively charged) that fall within the scope of the claim cannot be ascertained.

10. Applicant's arguments regarding the 35 U.S.C. 103 rejections of claims 6 and 12 presented on pages 7-9 of Amdt. D have been fully considered but are not persuasive.

On page 7 of Amdt. D, Applicant argues that Applicant argues that Waki et al. "does not disclose or suggest that at least an inner surface of the container is coated beforehand", but this argument is irrelevant since each of the primary references teach that the inner surfaces of the containers taught by the respective primary references are hydrophilic, as made of record in paragraphs 8-10 of the Office Action mailed April 20, 2004. Applicant argues that the copolymer taught by Waki et al. is "soluble in water, not insoluble in water", but the claims do not require that the polymer be insoluble in water. Applicant argues that Waki et al. do not "disclose or suggest" the claimed maximum saturation adsorption amount, but it is not stated in paragraphs 8-

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10 of the previous Office Action mailed April 20, 2004 that Waki et al. do “disclose or suggest” the claimed maximum saturation adsorption amount. Applicant cites the data presented in Table 5 of Waki et al. in support of Applicant’s argument that “there is no reasonable expectation based on the disclosure of Waki et al that the saturation adsorption amount as presently claimed can ever be attained”, but the data presented in Table 5 is for three particular proteins (i.e. albumin,  $\gamma$ -globulin and fibrinogen, see column headings in Table 5) at two different blood concentrations (see col. 23, lines 11-15 and the subheadings of the Table which read “Concentration of Human Plasma Protein” and “Concentration of Human Plasma Protein (1/10)”: the “1/10” at the end of the second heading indicates that the blood concentration is diluted to one tenth the concentration of the first blood samples tested). Absorption data for three particular proteins, each at two particular concentrations, does not represent absorption data for all proteins for all possible concentrations. Furthermore, the “absorption” property determined by Waki et al. is not the same property as the claimed saturation adsorption amount.

### ***Conclusion***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is 571-272-1488. The examiner can normally be reached on Monday-Thursday from 9:00am to 6:00pm and on alternate Fridays from 9:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Walter B. Aughenbaugh  
06/02/05

WBA



WILLIAM P. WATKINS III  
PRIMARY EXAMINER

Acting For Harold Myer  
SPE 1772